

**Economic Impact Statement**

**June 24, 2021**

**Description of the Rule**

The Indiana Department of Health (the “Department”) is seeking to amend 410 IAC 3-3-3 to add to the list of disorders all newborns and infants shall be screened for and 410 IAC 3-3-13 to increase the fee charged for newborn screenings to cover the cost of screening for the new disorder.

**Economic Impact on Small Businesses**

- 1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

**IC 5-28-2-6 defines a small business as a business entity that satisfies the following requirements:**

- (1) On at least fifty percent (50%) of the working days of the business entity occurring during the proceeding calendar year, the business entity employed not more than one hundred fifty (150) employees.**
- (2) The majority of the employees of the business entity work in Indiana.**

Response: There are approximately seven (7) licensed birthing centers that are subject to the rule. The eighty-six (86) Indiana hospitals that deliver babies, which are subject to this rule, do not meet the definition of a small business.

- 2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.**

Response: The proposed rule amendment will not impact any reporting, record keeping, or other administrative costs for small businesses. Birthing centers are only permitted to deliver a normal or uncomplicated pregnancy. Therefore, if a pregnant patient or infant is diagnosed prenatally with a medical condition, the delivery and any necessary treatment or procedures postnatally would occur at a hospital. These changes should not make a difference in how small businesses will comply with newborn screening requirements.

- 3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.**

Response: Compliance with the proposed rule amendment imposes no economic impact on small businesses. The seven licensed birthing centers are the only “small businesses” subject to the rule. Adding a new condition should not have a fiscal impact on a birthing center.

4. **Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.**

Response: The proposed rule amendment imposes no cost on small businesses.

5. **Regulatory Flexibility Analysis**

Response: No regulatory flexibility analysis is necessary because the proposed rule amendment imposes no costs on small businesses.